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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/791,592

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Israel R. Charo

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EXAMINER

BALLARD, KIMBERLY A

ART UNIT

PAPER NUMBER

1649

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/791,592

Applicant(s)

CHARO ET AL.

Examiner

Kimberly A. Ballard

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

The Examiner of U.S. Patent Application No. 10/791,592 has changed. In order to expedite the correlation of papers with the application, please direct all future correspondence to Examiner Ballard, Technology Center 1600, Art Unit 1649.

The Amendment and Remarks/Arguments filed September 23, 2005 are acknowledged. The Applicant has canceled claims 1-12 and claims 13-17 have been added. Claims 13-17 are pending and under examination in this office action.

### ***Priority***

Applicant's argument (dated 9/23/05) stating that the specification of the current application is identical to the specifications of the prior filed U.S. Applications going back to No. 08/182,962 filed on January 13, 1994 is noted, but is not found to be persuasive for all of the claims in the instant application. Support for an anti-MCP-1 antibody and a method of making the antibody can be found in the specification of the 08/182,962 application on lines 1-2, p. 9, which discloses compositions for use in therapy, diagnosis, assay of MCP-1R, or in raising antibodies to MCP-1R, comprising effective amounts of MCP-1R proteins prepared according to the foregoing processes. Support for the composition comprising an antibody specific to MCP-1 can be found on lines 11-14, p. 26 of the '962 application, reciting immunoassays using the anti-MCP-1

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antibodies. One of skill in the art would understand that the use of these antibodies for immunoassay would necessitate combining them with a pharmaceutically acceptable carrier (e.g. PBS). Therefore, claims 13, 16 and 17, reciting an antibody specifically binding to MCP-1 receptor, a composition comprising an antibody, and a method of making the antibody are clearly contemplated in the '962 application and will therefore be given the priority date of January 13, 1994.

However, support for claims 14-15 reciting a monoclonal antibody and a Fab antibody fragment, respectively, can only be determined to stem from the parent application, 09/625,573, filed July 25, 2000 (now U.S. Patent 6,730,301). The '301 patent provides evidence that the monoclonal antibodies (claim 8 of patent) and Fab fragments (claim 3 of patent) recited in claims 14-15 of the instant application had been previously contemplated. Applicant's argument that support for a monoclonal antibody can be found in a number of references well known in the art and cited in the 08/182,962 specification is not found to be persuasive. No specific mention of the word "monoclonal" antibody in the specification is ever presented until the 09/625,573 application, nor are any working or prophetic examples drawn to a monoclonal anti-MCP-1 antibody. Applicant's argument that the term "binding fragment" is supported in the 08/182,962 specification under the phrasing "MCP-1 antagonists and fragments thereof" is also not found to be persuasive by the Examiner. This phrasing and subsequent phrasing about MCP-1 antagonists (p. 26, for example) does not distinctly contemplate fragments of antibodies. Therefore, the present claims 14-15 will be given the priority date of July 25, 2000 in accord with the parent application 09/625,573.

***Specification***

The disclosure is objected to because of the following informalities: Application No. 09/625,573 as listed on p. 2, lines 4-5, has now been patented as U.S. Patent No. 6,730,301. Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The subject matter in claims 14-15 has no antecedent basis in the specification. Applicant's arguments that support for claims 14-15 can be found in the specification and incorporated references are not found persuasive. Applicant must amend the specification to provide direct support for these claims.

***Claim Rejections - 35 USC § 112***

The rejections of canceled claims 1-5 and 9-12 under 35 U.S.C. §112, first paragraph, as stated on pages 3-4 (for new matter) and pages 5-6 (for written description) of the previous Office Action dated June 21, 2005 are hereby withdrawn upon further consideration of this case.

The rejection of canceled claims 1 and 11 under 35 U.S.C. §112, first paragraph, as stated on pages 6-8 (for enablement) of the Office action dated June 21, 2005 is hereby withdrawn upon further consideration of this case and in view of Applicant's arguments.

***Claim Rejections - 35 USC § 102***

Applicant's argument (p. 8, from 9/23/05) that the rejection of canceled claims 1-5 and 9-12 under U.S.C. §102(b) as stated on pages 8-9 in the Office Action (dated 6/21/05) never qualified as a reference under 35 U.S.C. §102(b) has been noted. The rejection should have been made under 35 U.S.C. §102(e). In reconsideration of the priority dates noted above in the section "Priority", the rejection of canceled claim 1 is hereby withdrawn. However, the rejection of claims 2-5 and 9-12 under 35 U.S.C. §102(e) remains and is applied to new claims 14-15.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-15 are rejected under 35 U.S.C. §102(b) as being anticipated by Rodriguez-Frade et al. (March 1999, *Proc. Natl. Acad. Sci. USA*, 96: 3628-3633). As noted in the Priority section above, the priority date assigned to claims 14-16 is July 25, 2000 and for claims 13 and 16-17 the priority date is January 13, 1994. Hence, the dependent claims 14-15 are anticipated by prior art that would not anticipate the independent claim 13 or the dependent claims 16-17 with their earlier priority date.

Claims 14-15 are drawn to a monoclonal antibody which specifically binds MCP-1 receptor polypeptide, wherein the polypeptide comprises the amino acid sequence of SEQ ID NO:2 and Fab antibody fragments.

Rodriguez-Frade et al. teach the use of monoclonal antibodies directed the MCP-1 receptor, CCR2, as well as the production of Fab fragments (column 1, p. 3629). The monoclonal antibodies taught in Rodriguez-Frade et al. would meet the limitation of claim 14 because the binding to MCP-1 receptor is an inherent property of the antibodies. As further evidence that the antibodies generated from the CCR2 receptor of Rodriguez-Frade et al. would specifically bind MCP-1 receptor polypeptide, the sequences used to generate the monoclonal antibodies, amino acid sequences 24-38 and 273-292 of the CCR2 receptor polypeptide (see Rodriguez-Frade et al., 1997, *J. Immunology*, 159: 5576-5584 for methodology), are an exact match when compared to amino acid residues 24-38 and 273-292 of SEQ ID NO:2 of the present application. For example, PCT Application WO 97/31949 (published 9/4/97), Lind et al., which lists Rodriguez-Frade as an inventor, recites amino acids 24-38 as FDYDYGAPCHKFDVK and amino acids 273-292 as GLSNCESTSQLDQATQVTET (see p. 13, Example 1), which exactly match the corresponding amino acid sequences of SEQ ID NO:2 of the instant application. Because no further specificity in binding is recited by the monoclonal antibody of claim 14, the Fab fragment of claim 15, or the antibody in the composition of claim 16 other than specifically binding to MCP-1 receptor polypeptide, wherein the polypeptide comprises the amino acid sequence of SEQ ID NO:2, these limitations would be met by the Rodriguez-Frade et al. (1999) reference.

***Conclusion***

Claims 13, 16 and 17 are subject to allowability with minor revisions. Claims 14 and 15 are not allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following references are of interest because they disclose information and/or claims related to antibodies of the MCP-1 receptor, CCR2, however because of their publication dates, not all of the references qualify as prior art.

U.S. Patent No. 6,312,689 B1, LaRosa GJ, issued November 6, 2001.

U.S. Patent No. 6,696,550 B2, LaRosa GJ et al., issued February 24, 2004.

U.S. Patent No. 6,084,075 (filed 2/28/97), Lind et al., issued July 4, 2000.

U.S. Patent No. 6,600,030 B2 (filed 8/10/98), Dean et al., issued July 29, 2003.




***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Ballard whose telephone number is 571-272-4479. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kimberly Ballard, PhD  
Art Unit 1649  
November 3, 2005

  
JANET L. ANDRES  
SUPERVISORY PATENT EXAMINER